

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k150132

B. Purpose for Submission:

New Device

C. Measurand:

Quality Control material for IMMULITE IGF-I and IGFBP-3 assays
Quality Control material for IMMULITE Gastrin assay

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc

F. Proprietary and Established Names:

IMMULITE IGF Control Module, IMMULITE Gastrin Control Module

G. Regulatory Information:

1. Regulation section:

21CFR § 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class I, Reserved

3. Product code:

JJX

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use statements below.

2. Indication(s) for use:

IMMULITE IGF Control Module is an assayed, bi-level control intended for use with IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGF-I, and IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGFBP-3 assays. It is intended as an aid in monitoring day-to-day assay performance.

IMMULITE Gastrin Control Module is an assayed, bi-level control intended for use with the IMMULITE/IMMULITE 1000 and IMMULITE 2000 Gastrin assay. It is intended as an aid in monitoring day-to-day assay performance.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

IMMULITE/IMMULITE 1000 and IMMULITE 2000

I. Device Description:

IMMULITE IGF Control Module contains one set of 2 vials, each 4.0mL after reconstitution with distilled or deionized water, containing lyophilized IGF-I and IGFBP-3 in a protein buffer matrix with preservatives.

IMMULITE Gastrin Control Module contains one set of 2 vials, each 2.0mL after reconstitution with distilled or deionized water, containing lyophilized synthetic-human G-17 gastrin in a buffer matrix with preservatives.

The sponsor has the following caution statement in their labeling: Each human donor unit used to manufacture this control was tested by FDA approved methods or equivalent and found to be non-reactive for Syphilis, Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1 /HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

IMMULITE SHBG Controls

2. Predicate 510(k) number(s):

k955440

3. Comparison with predicate:

IMMULITE IGF Control Module:

SIMILARITIES		
	Candidate Device IMMULITE IGF Control Module	Predicate Device IMMULITE SHBG Controls k955440
Intended Use	It is intended for use as quality control material in monitoring day-to-day assay performance.	Same
Form	Lyophilized	Same
Stability	Stable unopened until the expiration date	Same
Levels	2	Same
Matrix	Bovine protein/buffer matrix with preservatives	Same

DIFFERENCES		
	Candidate Device IMMULITE IGF Control Module	Predicate Device IMMULITE SHBG Controls k955440
Analyte(s)	IGF-I and IGFBP-3	SHBG
Storage	-20°C for 30 days after reconstitution (aliquoted)	2 -8°C for 30 days after reconstitution or at -20°C

IMMULITE Gastrin Control Module:

SIMILARITIES		
	Candidate Device IMMULITE Gastrin Control Module	Predicate Device IMMULITE SHBG Controls k955440
Intended Use	It is intended for use as quality control material in monitoring day-to- day assay performance.	Same
Form	Lyophilized	Same
Levels	2	Same
Stability	Stable unopened until the expiration date	Same

DIFFERENCES		
	Candidate Device IMMULITE® Gastrin Control Module	Predicate Device IMMULITE SHBG Controls k955440
Analyte	Gastrin	SHBG
Matrix	Buffered matrix	Non-human (bovine)protein/buffer matrix
Storage	-20°C for 30 days after reconstitution (aliquoted)	2 -8°C for 30 days after reconstitution or at -20°C for 6 months (aliquoted)

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability and Value assignment:

The IMMULITE IGF-I controls are value assigned using assigned reference controls. The assigned reference controls are prepared using IGF-I and IGFBP-3 antigen stock. Human Recombinant IGF-I antigen and IGF-I/IGFBP-3 positive human serum are used. IGF-I and IGF BP-3 antigens are sourced from commercially available vendors with high purity. IGF controls are required to have a minimum of 100 control points from at least 3 kit lots and 3 instruments on both IMMULITE/IMMULITE 1000 and IMMULITE 2000 platforms and for both IGF-I and IGFBP-3. The control mean values are based on the calculated averaged values from all the instruments. Control mean values and 2 SD control ranges for one reagent lot are shown below.

IGF-I:

Control Level	Mean (ng/mL)	2SD Range (ng/mL)
1	91	73-109
2	277	222-332

IGFBP-3:

Control Level	Mean (ng/mL)	2SD Range (ng/mL)
1	1.10	0.86 – 1.34
2	4.4	3.6 – 5.2

The IMMULITE Gastrin controls are value assigned using assigned reference controls. The assigned reference controls are prepared using gastrin antigen stock. Gastrin antigen is sourced from a commercially available vendor with high purity. Gastrin controls are required to have a minimum of 100 control points from at least 3 kit lots and 3 instruments on both IMMULITE/IMMULITE 1000 and IMMULITE 2000 platforms. The control mean values are based on the calculated averaged values from all the instruments. Control mean values and 2 SD control ranges for one reagent lot are shown below.

Gastrin:

Control Level	Mean (pg/mL)	2SD Range (pg/mL)
1	94	82 - 106
2	364	306 – 422

Stability:

Shelf-Life and Open Vial Stability testing protocols and acceptance criteria for the IMMULITE IGF Control Module were described and found to be adequate. The real time stability study shows study results up to 3 years when stored at 2 - 8 °C supporting the claim of 3 years shelf life from date of manufacture when stored at 2 - 8 °C prior to opening. The open vial stability study shows study results up to 35 days at -20°C supporting the claim of 30 days after opening and reconstitution if aliquoted and frozen immediately at -20°C.

Shelf-Life and Open Vial Stability testing protocols and acceptance criteria for the IMMULITE Gastrin Control Module were described and found to be adequate. The real time stability study shows study results up to 3 years when stored at 2 - 8 °C supporting the claim of 3 years shelf life from date of manufacture when stored at 2 - 8 °C prior to opening. The open vial stability study shows study results up to 35 days at -20°C supporting the claim of 30 days after opening and reconstitution if aliquoted and frozen immediately at -20°C.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

See individual package insert

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.